

Related U.S. Application Data

continuation of application No. 13/620,519, filed on Sep. 14, 2012, now Pat. No. 8,457,759, which is a continuation of application No. 12/499,769, filed on Jul. 8, 2009, now Pat. No. 8,311,639.

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(56)

References Cited

U.S. PATENT DOCUMENTS

5,643,330 A 7/1997 Holsheimer et al.
 5,782,884 A 7/1998 Stotts et al.
 5,891,179 A 4/1999 Er et al.
 5,938,690 A 8/1999 Law
 6,052,624 A 4/2000 Mann
 6,236,892 B1 5/2001 Feler
 6,393,325 B1 5/2002 Mann et al.
 6,461,357 B1 10/2002 Sharkey et al.
 6,584,358 B2 6/2003 Carter et al.
 6,622,048 B1 9/2003 Mann et al.
 6,687,538 B1 2/2004 Hrdlicka et al.
 6,760,627 B2 7/2004 Carter et al.
 6,792,315 B2 9/2004 Carter et al.
 6,853,863 B2 2/2005 Carter et al.
 6,895,280 B2 5/2005 Meadows et al.
 6,909,917 B2 6/2005 Woods et al.
 6,947,792 B2 9/2005 Ben-Haim et al.
 6,978,171 B2 12/2005 Goetz et al.
 6,993,384 B2 1/2006 Bradley et al.
 7,020,523 B1 3/2006 Lu et al.
 7,024,246 B2 4/2006 Acosta et al.
 7,174,215 B2 2/2007 Bradley
 7,289,851 B2* 10/2007 Gunderson et al. 607/27
 7,317,948 B1 1/2008 King et al.
 7,444,181 B2 10/2008 Shi et al.
 7,447,545 B2 11/2008 Heruth et al.
 7,489,970 B2 2/2009 Lee et al.
 7,493,159 B2 2/2009 Hrdlicka et al.
 7,555,346 B1 6/2009 Woods et al.
 7,720,548 B2 5/2010 King
 7,742,823 B2 6/2010 King et al.
 7,853,330 B2 12/2010 Bradley et al.
 7,872,884 B2 1/2011 Parramon et al.
 7,957,797 B2 6/2011 Bourget et al.
 7,957,809 B2 6/2011 Bourget et al.
 7,957,814 B2 6/2011 Goetz et al.
 8,016,776 B2 9/2011 Bourget et al.
 8,108,049 B2 1/2012 King
 8,116,878 B1 2/2012 Palmer
 8,121,703 B1 2/2012 Palmer
 8,311,639 B2 11/2012 Parker et al.
 8,355,797 B2 1/2013 Caparso et al.
 8,457,759 B2 6/2013 Parker et al.
 8,498,710 B2 7/2013 Walker et al.
 8,626,312 B2 1/2014 King et al.
 8,712,533 B2 4/2014 Alataris et al.
 8,712,535 B2 4/2014 Walker et al.
 9,061,154 B2 6/2015 Parker et al.
 2002/0068930 A1 6/2002 Tasto et al.
 2003/0195582 A1 10/2003 Mann
 2004/0116978 A1 6/2004 Bradley
 2004/0167584 A1 8/2004 Carroll et al.
 2004/0172100 A1 9/2004 Humayun et al.
 2005/0060007 A1 3/2005 Goetz
 2006/0116742 A1 6/2006 De Ridder
 2006/0195159 A1 8/2006 Bradley et al.
 2006/0224187 A1 10/2006 Bradley et al.
 2006/0253174 A1 11/2006 King
 2006/0259099 A1 11/2006 Goetz et al.
 2006/0264777 A1 11/2006 Drew
 2007/0039625 A1 2/2007 Heruth et al.
 2007/0073357 A1 3/2007 Rooney et al.

2007/0150029 A1 6/2007 Bourget et al.
 2007/0156207 A1 7/2007 Kothandaraman et al.
 2007/0179579 A1 8/2007 Feler et al.
 2007/0208394 A1 9/2007 King et al.
 2007/0213789 A1 9/2007 Nolan et al.
 2007/0249968 A1 10/2007 Miesel et al.
 2007/0265681 A1 11/2007 Gerber et al.
 2007/0276450 A1 11/2007 Meadows et al.
 2008/0015657 A1 1/2008 Haefner
 2008/0046036 A1 2/2008 King et al.
 2008/0064980 A1 3/2008 Lee et al.
 2008/0071325 A1 3/2008 Bradley
 2008/0154340 A1 6/2008 Goetz et al.
 2008/0183256 A1 7/2008 Keacher
 2008/0188909 A1 8/2008 Bradley
 2008/0215118 A1 9/2008 Goetz et al.
 2008/0281381 A1 11/2008 Gerber et al.
 2008/0319511 A1 12/2008 Pless
 2008/0319514 A1 12/2008 Shi et al.
 2009/0018617 A1 1/2009 Skelton et al.
 2009/0125079 A1 5/2009 Armstrong et al.
 2009/0264956 A1 10/2009 Rise et al.
 2009/0306746 A1 12/2009 Blischak
 2009/0326608 A1 12/2009 Huynh et al.
 2010/0049280 A1 2/2010 Goetz
 2010/0069993 A1 3/2010 Greenspan
 2010/0121408 A1 5/2010 Imran et al.
 2010/0137944 A1 6/2010 Zhu
 2010/0185256 A1 7/2010 Hulvershorn
 2010/0274312 A1 10/2010 Alataris et al.
 2010/0274314 A1 10/2010 Alataris et al.
 2010/0274317 A1 10/2010 Parker et al.
 2010/0305631 A1 12/2010 Bradley et al.
 2011/0009927 A1 1/2011 Parker et al.
 2011/0040351 A1 2/2011 Butson et al.
 2011/0093051 A1 4/2011 Davis et al.
 2011/0184488 A1 7/2011 De Ridder
 2012/0083857 A1 4/2012 Bradley et al.
 2012/0116476 A1 5/2012 Kothandaraman
 2012/0130448 A1 5/2012 Woods et al.
 2012/0172946 A1 7/2012 Alataris et al.
 2012/0253422 A1 10/2012 Thacker et al.
 2012/0265268 A1 10/2012 Blum et al.
 2012/0265271 A1 10/2012 Goetz
 2013/0023950 A1 1/2013 Gauthier
 2013/0060302 A1 3/2013 Polefko et al.
 2013/0116752 A1 5/2013 Parker et al.
 2013/0261694 A1 10/2013 Caparso et al.
 2013/0310892 A1 11/2013 Parker et al.
 2014/0081349 A1 3/2014 Lee et al.
 2014/0330338 A1 11/2014 Walker et al.
 2015/0217113 A1 8/2015 Walker et al.

FOREIGN PATENT DOCUMENTS

JP 2006502811 A 1/2006
 JP 2006212458 A 8/2006
 JP 2008526299 A 7/2008
 JP 2008534168 A 8/2008
 JP 2009519771 A 5/2009
 WO WO-2006119046 A1 11/2006
 WO WO-2007149018 A1 12/2007
 WO WO-2008142402 A1 11/2008

OTHER PUBLICATIONS

International Search Report and Written Opinion for International Application No. PCT/US2010/040081, Applicant: Nevro Corporation, mailed Oct. 26, 2010, 16 pages.
 Keuchmann C et al., "853 Could Automatic Position Adaptive Stimulation be Useful in Spinal Cord Stimulation," Abstract, Medtronic, Inc., undated, 1 page.
 Hayt et al., "Engine Circuit Analysis," McGraw-Hill Book Company, Fourth Edition, 1986, 18 pages.
 Notice of Opposition to a European Patent for European Patent No. 2043589, Proprietor of the Patent: Nevro Corporation; Opponent: Boston Scientific Neuromodulation Corporation, Oct. 22, 2014, 32 pages.

(56)

References Cited

OTHER PUBLICATIONS

Notice of Opposition to a European Patent for European Patent No. 2043589, Proprietor of the Patent: Nevro Corporation, Opponent: Medtronic, Inc., Oct. 13, 2014, 20 pages.

Notice of Opposition to a European Patent, Argument and Facts, for European Patent No. 2459271, Proprietor of the Patent: Nevro Corporation; Opponent: Boston Scientific Neuromodulation Corporation, Jan. 20, 2016, 22 pages.

* cited by examiner

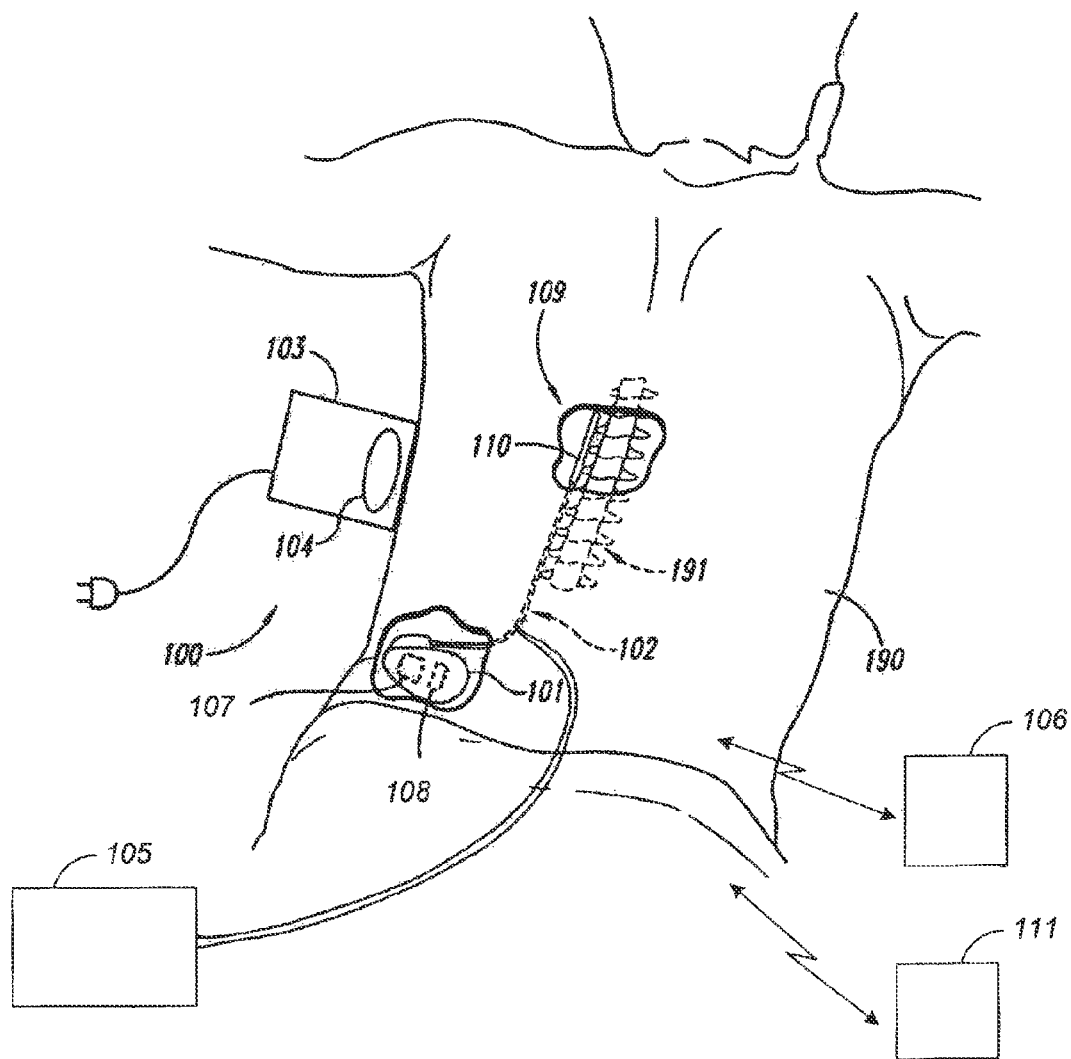


FIG. 1A

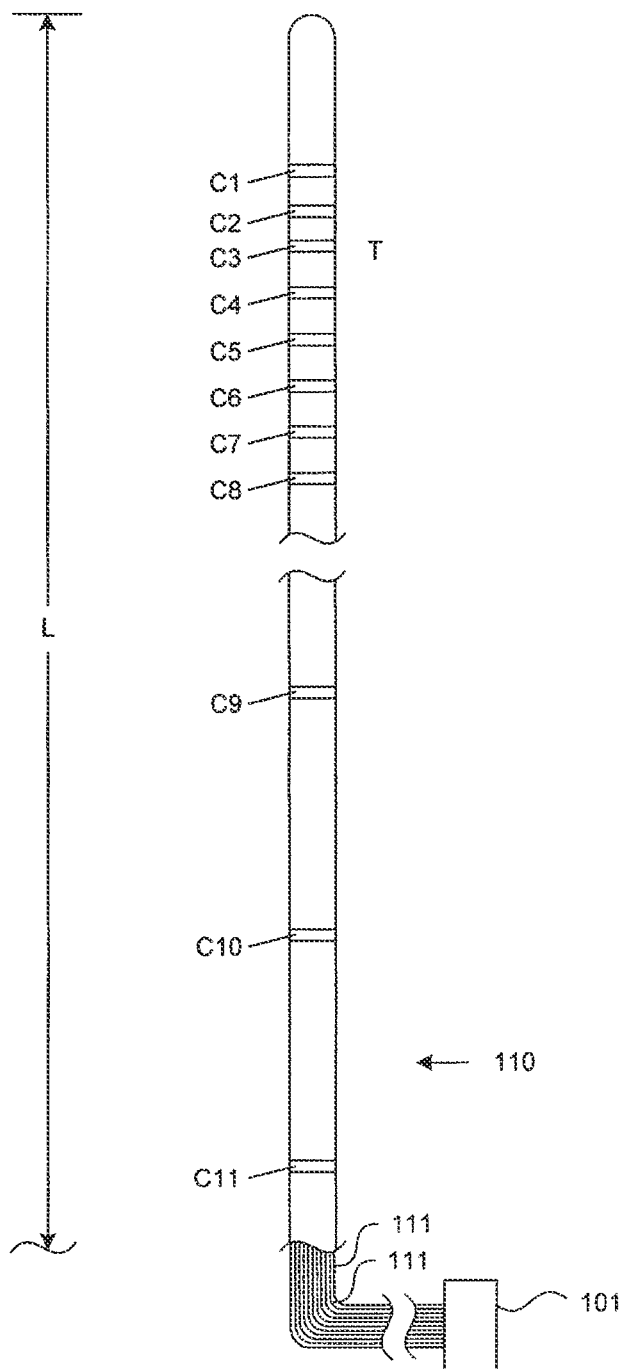
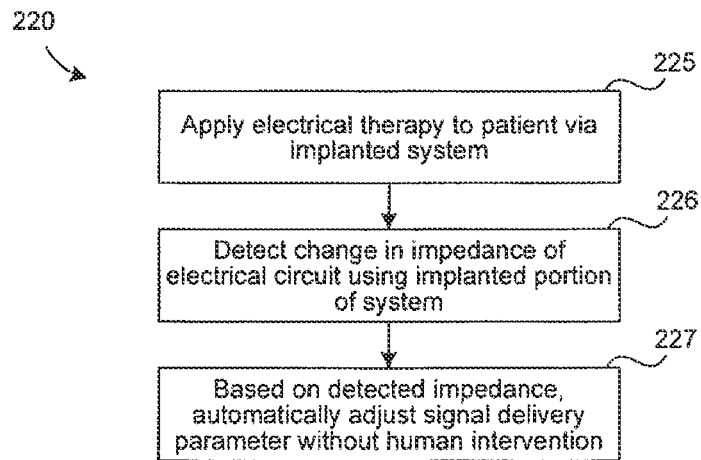
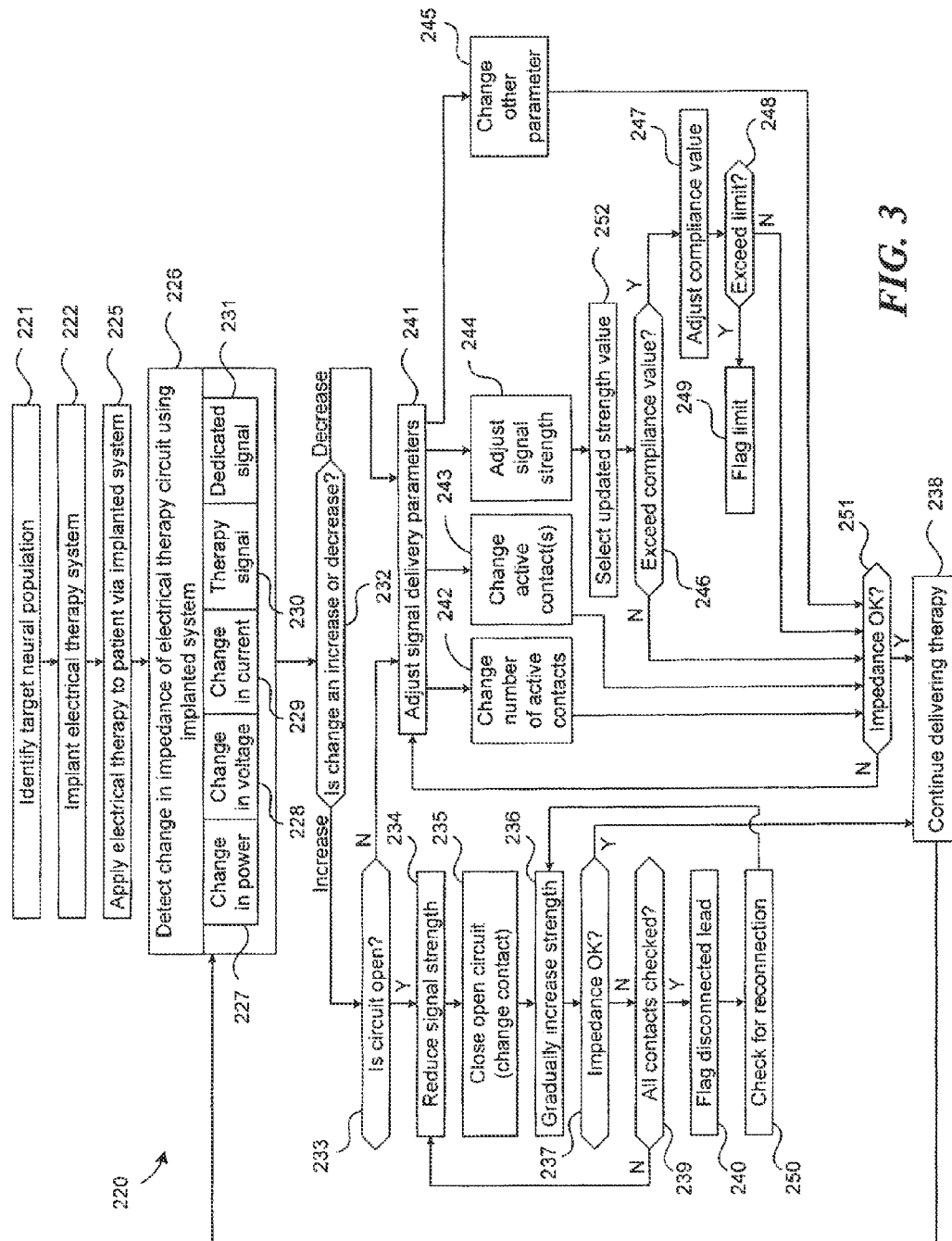


FIG. 1B

**FIG. 2**



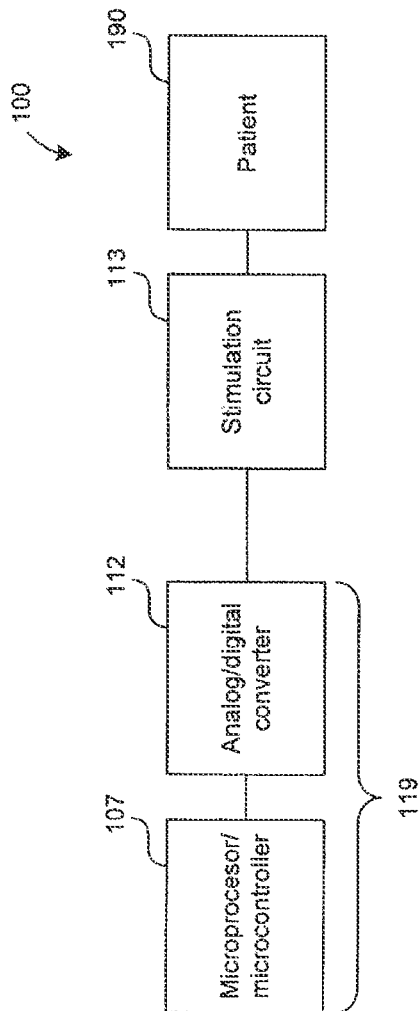


FIG. 4A

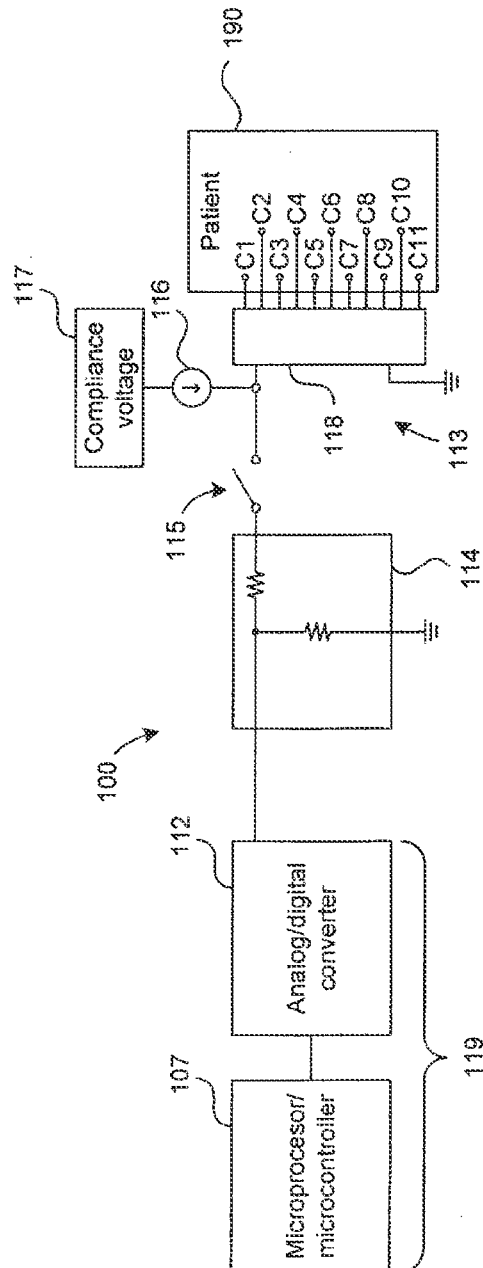


FIG. 4B

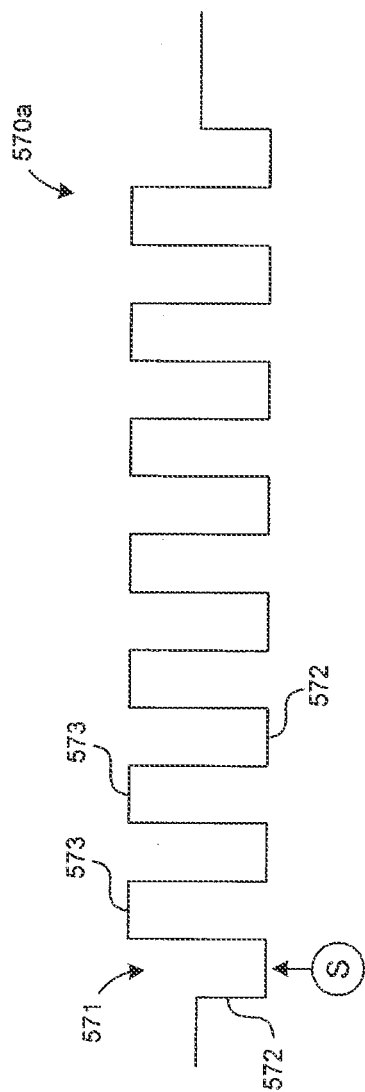


FIG. 5A

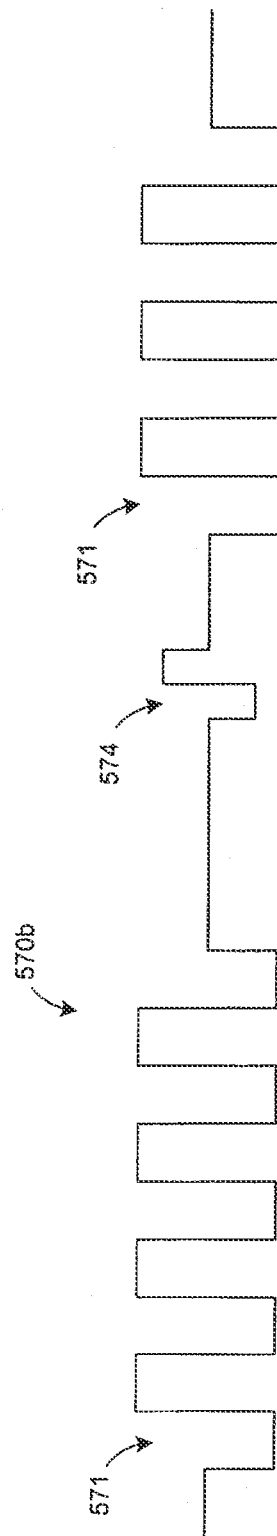
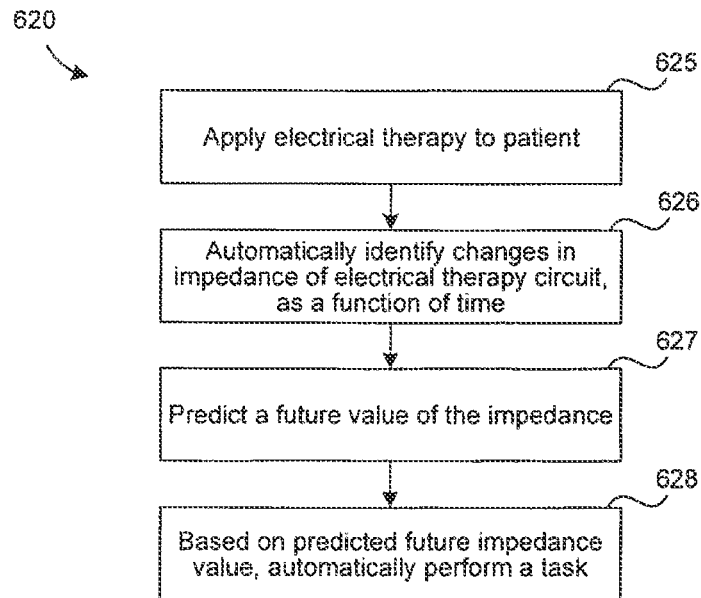


FIG. 5B

**FIG. 6**

SYSTEMS AND METHODS FOR ADJUSTING ELECTRICAL THERAPY BASED ON IMPEDANCE CHANGES

CROSS-REFERENCE TO RELATED APPLICATION(S)

This is a continuation application of U.S. patent application Ser. No. 14/149,654, filed Jan. 7, 2014, entitled SYSTEMS AND METHODS FOR ADJUSTING ELECTRICAL THERAPY BASED ON IMPEDANCE CHANGES, which is a continuation of U.S. patent application Ser. No. 13/908,817, filed Jun. 3, 2013, now U.S. Pat. No. 8,639,351, issued Jan. 28, 2014, and entitled SYSTEMS AND METHODS FOR ADJUSTING ELECTRICAL THERAPY BASED ON IMPEDANCE CHANGES, which is a continuation of U.S. patent application Ser. No. 13/620,519, filed Sep. 14, 2012, now U.S. Pat. No. 8,457,759, issued Jun. 4, 2013, and entitled SYSTEMS AND METHODS FOR ADJUSTING ELECTRICAL THERAPY BASED ON IMPEDANCE CHANGES, which is a continuation of U.S. patent application Ser. No. 12/499,769, filed Jul. 8, 2009, now U.S. Pat. No. 8,311,639, issued Nov. 13, 2012, and entitled SYSTEMS AND METHODS FOR ADJUSTING ELECTRICAL THERAPY BASED ON IMPEDANCE CHANGES, each of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present disclosure is directed generally to systems and methods for adjusting electrical therapy provided to patients, based on changes in the impedance of circuits providing the therapy, including changes detected while applying therapeutic electrical signals to a patient's spinal cord.

BACKGROUND

Neurological stimulators have been developed to treat pain, movement disorders, functional disorders, spasticity, cancer, cardiac disorders, and various other medical conditions. Implantable neurological stimulation systems generally have an implantable pulse generator and one or more leads that deliver electrical pulses to neurological tissue or muscle tissue. For example, several neurological stimulation systems for spinal cord stimulation (SCS) have cylindrical leads that include a lead body with a circular cross-sectional shape and one or more conductive rings spaced apart from each other at the distal end of the lead body. The conductive rings operate as individual electrodes and, in many cases, the SCS leads are implanted percutaneously through a large needle inserted into the epidural space, with or without the assistance of a stylet.

Once implanted, the pulse generator applies electrical pulses to the electrodes, which in turn modify the function of the patient's nervous system, such as by altering the patient's responsiveness to sensory stimuli and/or altering the patient's motor-circuit output. In pain treatment, the pulse generator applies electrical pulses to the electrodes, which in turn can generate sensations that mask or otherwise alter the patient's sensation of pain. For example, in many cases, patients report a tingling or paresthesia that is perceived as more pleasant and/or less uncomfortable than the underlying pain sensation.

One problem associated with existing stimulation systems is that aspects of the systems and/or the interactions between the systems and the patient may change over time. For example, the impedance of a stimulation circuit (which includes implanted electrodes and the patient's tissue) can

change as scar tissue forms at the implant site and/or if the lead moves within the patient, and/or if the lead becomes disconnected or undergoes other changes. As the circuit impedance changes, the strength of the applied signal changes, which can reduce the efficacy of the signal and/or create patient discomfort. Accordingly, there remains a need for improved techniques and systems for addressing patient pain in a manner that is effective and comfortable over an extended period of time.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a partially schematic illustration of an implantable spinal cord stimulation system positioned at the spine to deliver therapeutic signals in accordance with an embodiment of the present disclosure.

FIG. 1B is a partially schematic illustration of a lead having electrode contacts that form elements of one or more therapy circuits having impedances that are detected in accordance with methods of the present disclosure.

FIG. 2 is a flow diagram illustrating a process for adjusting electrical therapy parameters in response to detected changes in therapeutic circuit impedance.

FIG. 3 is a flow diagram illustrating further details of processes for detecting and responding to changes in therapy circuit impedance, in accordance with further embodiments of the disclosure.

FIG. 4A is a schematic illustration of a representative detection system in accordance with an embodiment of the disclosure.

FIG. 4B is a schematic illustration of a representative circuit for detecting impedance changes in accordance with another embodiment of the disclosure.

FIGS. 5A and 5B are schematic illustrations of waveforms indicating points at which impedance detection may be performed in accordance with embodiments of the disclosure.

FIG. 6 is a flow diagram illustrating a process for predicting future values of impedance based on impedance trends in accordance with an embodiment of the disclosure.

DETAILED DESCRIPTION

The present disclosure is directed generally to systems and methods for adjusting electrical therapy parameters based on detected changes in the impedance of an electrical circuit that provides the electrical therapy. Specific details of certain embodiments of the disclosure are described below with reference to adjusting therapy parameters for spinal cord stimulators, which may be used to treat chronic pain. However, the disclosed systems and methods may be used in the context of other stimulators and/or other patient conditions. Accordingly, some embodiments can have configurations, components, or procedures different than those described in this section, and other embodiments may eliminate particular components or procedures. A person of ordinary skill in the relevant art, therefore, will understand that the invention may have other embodiments with additional elements, and/or may have other embodiments without several of the features shown and described below with reference to FIGS. 1A-6.

Overview

During the course of a typical spinal cord stimulation therapy regimen and/or a trial period leading up to the therapy regimen, the impedance of the electrical circuit that provides electrical therapy to the patient may change for any variety of reasons. For example, if the patient changes position and the implanted lead carrying the therapy electrodes shifts, the circuit impedance may change because the electrodes are now

adjacent to tissue and/or fluid having different impedance characteristics. If the circuit impedance changes suddenly, the patient may experience a sudden change in the applied current and/or voltage, potentially causing patient discomfort. In other cases, scar tissue may be present at implant and/or build up on the electrodes, decreasing the efficacy with which the electrical signals are provided to the patient. In still other cases, individual electrodes may short together, or the lead may become disconnected or partially disconnected from the signal generator, creating one or more open circuits that reduce or eliminate the efficacy of the therapy. In any of these instances, certain aspects of the following disclosure can automatically detect changes in circuit impedance and automatically respond to the changes in a manner that improves patient comfort and/or improves the efficacy of the therapy.

A method in accordance with a particular embodiment of the disclosure includes applying a therapeutic electrical signal to a patient via an implanted portion of a patient stimulation system that includes a signal delivery device in electrical communication with a target neural population of the patient. The electrical signal is delivered in accordance with one or more signal delivery parameters. The method can further include detecting a change in the impedance of an electrical circuit that includes the signal delivery device, using the implanted portion of the patient stimulation system. Based at least in part on the detected impedance change, the method can still further include automatically adjusting the value of the signal delivery parameter(s) without human intervention. Accordingly, the process of detecting impedance changes and responding to the detected changes can be performed autonomously by the implanted portion of the patient stimulation system.

A method in accordance with another aspect of the disclosure includes automatically identifying changes in the impedance of an electrical circuit that provides therapy to the patient, as a function of time. Based at least upon identifying the changes in impedance as a function of time, the method can further include predicting a future value of the impedance and automatically performing a task based on the predicted future value. Representative tasks include predicting a lead failure, confirming that an identified impedance trend conforms with an expected trend, and/or providing notice to a patient or practitioner of a predicted change in impedance value.

Representative Systems and Methods

In the following discussion, FIGS. 1A-1B illustrate a representative implementation of a system implanted in the patient's spinal cord region, and FIGS. 2-6 illustrate representative methods and associated circuits and waveforms for detecting impedance changes and responding to the detected changes. FIG. 1A schematically illustrates a representative treatment system **100** for providing relief from chronic pain and/or other conditions, arranged relative to the general anatomy of a patient's spinal cord **191**. The system **100** can include a pulse generator **101**, which may be implanted subcutaneously within a patient **190** and coupled to a signal delivery element **109**. In a representative example, the signal delivery element **109** includes a lead or lead body **110** that carries features or elements for delivering therapy to the patient **190** after implantation. The pulse generator **101** can be connected directly to the lead body **110**, or it can be coupled to the lead body **110** via a communication link **102** (e.g., an extension). As used herein, the terms lead and lead body include any of a number of suitable substrates and/or support members that carry devices for providing therapy signals to the patient **190**. For example, the lead body **110** can include

one or more electrodes or electrical contacts that direct electrical signals into the patient's tissue, such as to provide for patient relief. In other embodiments, the signal delivery element **109** can include devices other than a lead body (e.g., a paddle) that also direct electrical signals and/or other types of signals to the patient **190**.

The pulse generator **101** can transmit signals to the signal delivery element **109** that up-regulate (e.g., stimulate or excite) and/or down-regulate (e.g., block or suppress) target nerves. As used herein, and unless otherwise noted, the terms "stimulate" and "stimulation" refer generally to signals that have either type of effect on the target nerves. The pulse generator **101** can include a machine-readable (e.g., computer-readable) medium containing instructions for generating and transmitting suitable therapy signals. The pulse generator **101** and/or other elements of the system **100** can include one or more processors **107**, memories **108** and/or input/output devices. Accordingly, the process of determining impedance and taking follow-up action can be performed by computer-executable instructions contained on computer-readable media, e.g., the processor(s) **107** and/or memory(s) **108**. The pulse generator **101** can include multiple portions, elements, and/or subsystems (e.g., for directing signals in accordance with multiple signal delivery parameters), housed in a single housing, as shown in FIG. 1A, or in multiple housings. In any of these embodiments, the pulse generator **101** and/or other implanted components of the system **100** can include elements for detecting and responding to impedance changes.

In some embodiments, the pulse generator **101** can obtain power to generate the therapy signals from an external power source **103**. The external power source **103** can transmit power to the implanted pulse generator **101** using electromagnetic induction (e.g., RF signals). For example, the external power source **103** can include an external coil **104** that communicates with a corresponding internal coil (not shown) within the implantable pulse generator **101**. The external power source **103** can be portable for ease of use.

In another embodiment, the pulse generator **101** can obtain the power to generate therapy signals from an internal power source, in addition to or in lieu of the external power source **103**. For example, the implanted pulse generator **101** can include a non-rechargeable battery or a rechargeable battery to provide such power. When the internal power source includes a rechargeable battery, the external power source **103** can be used to recharge the battery. The external power source **103** can in turn be recharged from a suitable power source (e.g., conventional wall power).

In some cases, an external programmer **105** (e.g., a trial stimulator) can be coupled to the signal delivery element **109** during an initial implant procedure, prior to implanting the pulse generator **101**. For example, a practitioner (e.g., a physician and/or a company representative) can use the external programmer **105** to vary the stimulation parameters provided to the signal delivery element **109** in real time, and select optimal or particularly efficacious parameters. During this process, the practitioner can also vary the position of the signal delivery element **109**. After the position of the signal delivery element **109** and appropriate signal delivery parameters are established using the external programmer **105**, the patient **190** can receive therapy via signals generated by the external programmer **105**, generally for a limited period of time. In a representative application, the patient **190** receives such therapy for one week. Assuming the trial therapy is effective or shows the promise of being effective, the practitioner then replaces the external programmer **105** with the implanted pulse generator **101**, and programs the pulse gen-

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erator **101** with parameters selected based on the experience gained during the trial period. Optionally, the practitioner can also replace the signal delivery element **109**. Once the implantable pulse generator **101** has been positioned within the patient **190**, the signal delivery parameters provided by the pulse generator **101** can still be updated remotely via a wireless physician's programmer (e.g., a physician's remote) **111** and/or a wireless patient programmer **106** (e.g., a patient remote). Generally, the patient **190** has control over fewer parameters than does the practitioner. For example, the capability of the patient programmer **106** may be limited to starting and/or stopping the pulse generator **101**, and/or adjusting stimulation amplitude.

In any of the foregoing embodiments, the parameters in accordance with which the pulse generator **101** provides signals can be modulated during portions of the therapy regimen. For example, the frequency, amplitude, pulse width, duty cycle, and/or signal delivery location can be modulated in accordance with a preset program, patient and/or physician inputs, and/or in a random or pseudorandom manner. Such parameter variations can be used to address a number of potential clinical situations, including changes in the patient's perception of pain, changes in the preferred target neural population, and/or patient accommodation or habituation. Such parameter changes can also be implemented automatically to account for detected impedance changes.

FIG. 1B illustrates a representative lead **110** that can be connected to the pulse generator **101**. The lead **110** can have any suitable number of contacts **C** positioned along its length **L** for delivering electrical therapy to the patient. For purposes of illustration, 11 contacts **C**, identified individually as contacts **C1**, **C2** . . . **C11** are shown in FIG. 1B. In operation, one or more of the contacts **C** is cathodic and another one or more of the contacts **C** is anodic. The contacts **C** can be individually addressable so that any contact **C** or combination of contacts **C** can operate as a cathode, and any contact **C** or combination of contacts **C** can operate as an anode. The contacts **C** can be electrically grouped in any of a wide variety of combinations, and individual contacts **C** can perform different functions (e.g., cathodic functions and/or anodic functions) at different times during the course of a therapy regimen. In any of these embodiments, each contact **C** may be coupled with a corresponding conductor **111** to the pulse generator **101**. The conductors **111** may have one or more connection points along their lengths (e.g., at a junction with the pulse generator **101**, and optionally at a junction with an extension). Accordingly, the circuit for a given pair of contacts **C** includes the contacts **C**, the patient tissue **T** between the contacts, the individual conductors **111**, connection points along the conductors **111**, and connection points between the conductors **111** and the pulse generator **101**. As discussed below, aspects of the present disclosure are directed to detecting changes in the overall circuit impedance that may result from changes at any of a variety of points along the circuit, and providing an appropriate response.

FIG. 2 illustrates an overall process **220** in accordance with a particular embodiment of the disclosure. The process **220** includes applying electrical therapy to a patient via an implanted or partially implanted system (process portion **225**). During the course of the therapy, the process **220** can further include detecting a change in the impedance of an electrical circuit that provides the therapy, using the implanted portion of the system (process portion **226**). Based on the detected impedance change, the process **220** can still further include automatically adjusting signal delivery parameters in accordance with which the therapy is provided, without human intervention (process portion **227**). The signal

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delivery parameters can include signal strength, the location and/or number of electrical contacts delivering therapy to the patient, and/or other parameters. FIG. 3 describes further aspects of particular embodiments of the foregoing process.

FIG. 3 is a block diagram illustrating in further detail aspects of the overall process **220** described above with reference to FIG. 2. Process portion **221** includes identifying a target neural population. For example, process portion **221** can include identifying one or more neural populations at particular vertebral locations along the patient's spine. Process portion **222** includes implanting an electrical therapy system, for example, implanting the signal delivery element **109** and the pulse generator **101** described above with reference to FIGS. 1A and 1B. As discussed above with reference to FIG. 1B, the electrical therapy system includes at least one electrical therapy circuit which has associated with it an initial impedance value. In process portion **225**, electrical therapy is applied to the patient via the implanted system with the initial impedance value. The impedance value may change over time, which is detected in process portion **226**. The electrical therapy signals are typically time-varying signals (e.g., pulses), and the associated circuit can include capacitive and/or resistive elements. Accordingly, the detected impedance can include capacitive and/or resistive components. In particular embodiments, the system can distinguish between resistive and capacitive components of the overall impedance, and use this information to select the appropriate signal delivery parameter to vary. For example, if the impedance change is primarily capacitive, changing the signal delivery frequency may have a greater effect than if the impedance change is primarily resistive.

The change in impedance of the electrical circuit can be detected by detecting a change in power applied to the circuit (process portion **227**), a change in voltage at one or more points along the circuit (process portion **228**), a change in current passing through the circuit (process portion **229**), and/or changes in other values. In a particular embodiment (process portion **230**), the impedance of the electrical therapy circuit is detected while the therapy signal is delivered, for example, by sampling the therapy signal itself. In other embodiments, a dedicated electrical signal can be applied to the electrical therapy circuit and sampled, so as to detect impedance and/or impedance changes, independent of the therapy signal (process portion **231**). Accordingly, this arrangement can be used to detect impedance and/or impedance changes of a therapy circuit without the need for the therapy signal to be active on the circuit at that time.

In any of the foregoing embodiments, the process **220** can include different steps depending upon the magnitude and/or direction of the impedance change. In a particular embodiment, process portion **232** can include determining whether the impedance change is an increase or a decrease. If the change is an increase, process portion **233** can include determining whether the circuit is open. An open circuit can be indicated by an infinite impedance, or by an impedance or impedance increase that exceeds a suitable threshold value.

Process portions **234-240** may be performed if, in process portion **233**, it is determined that the electrical therapy circuit is open. For example, process portion **234** can include reducing the signal strength (e.g., the applied current and/or voltage) prior to closing or attempting to close the open circuit (process portion **235**). In particular embodiments, process portion **234** can include reducing the signal strength to zero, or to a suitable non-zero value such that when the circuit is later closed, the patient does not receive an uncomfortable sensation. Process portion **235** can, for example, include changing one or more of the contacts (e.g., those shown in

FIG. 1B) that form a portion of the electrical therapy circuit. This change can be achieved by opening and closing appropriate switches at the pulse generator 101. Once the change has been made, process portion 236 can include gradually increasing the strength of the signal applied to the therapy circuit. By first reducing the signal strength (process portion 234) and then gradually increasing the signal strength after the change in the circuit has been made (process portion 236), the process 220 can avoid subjecting the patient to a sudden increase in the applied signal, which may cause patient discomfort.

Once the signal strength has been increased, process portion 237 can include checking the impedance to determine whether it has returned to its original level, or has otherwise achieved an acceptable level. This process can include checking the power, voltage, and/or current, as described above with reference to process portions 227-229. If the impedance is at an acceptable level, process portion 238 includes continuing to deliver the therapy. In addition, the patient and/or practitioner can be notified that a change has been made to account for the detected increase in impedance. The notification can take any of a variety of suitable forms, including a vibratory signal, and/or an internally stored signal that is downloaded external to the patient during a battery recharge operation or diagnostic operation. If the change did not result in an adequately improved impedance level, then in process portion 239, the system checks to determine whether all the contacts of the implanted lead have been checked. If not, the process returns to process portion 234 and a different contact is placed in the circuit. If, after all of the contacts have been checked and determined to form an open circuit, this can indicate that the lead is disconnected, which is flagged for the user and/or practitioner in process portion 240, using any suitable notification technique. In process portion 250, the system checks for lead reconnection, e.g., by rechecking all contacts for an open circuit. Once the lead has been reconnected, the system returns to process portion 236 so as to gradually increase signal strength.

If in process portions 232 and 233, the system determines that the impedance has decreased, or has increased but not so much as to indicate an open circuit, then in process portion 241, the signal delivery parameters are adjusted in an autonomous manner to bring the impedance values to acceptable levels. Process portion 241 can in turn include changing any of a variety of signal delivery parameters as identified by process portions 242-245. For example, process portion 242 can include changing the number of active contacts in the electrical therapy circuit. The number of active contacts may be increased in particular embodiments if the circuit impedance increases (e.g., to provide parallel electrical paths), and may be decreased in other embodiments if the impedance decreases. In a particular example, the patient may change position or the lead may change position relative to the patient such that the circuit impedance increases because the active contacts are now positioned adjacent to a portion of the patient tissue having a higher impedance. By increasing the number of active contacts, the resulting circuit can include portions of the patient tissue having a lower impedance. Of course, when such a change is made, it is made so that the resulting therapy is still applied to the appropriate portion of the patient tissue, even though the range over which the active contacts are positioned and may now be expanded. For example, only a subset of the contacts shown in FIG. 1B may be used and/or available for such a change, so as to avoid directing the therapy signal too far from the originally intended neural population.

In other embodiments, the system can automatically detect a decrease in the impedance of the therapy circuit. For example, if the lead shifts to a location within the patient that results in a lowered impedance, the system can automatically detect this occurrence. One such example is if the lead shifts from an initial position so as to be in closer proximity to cerebral spinal fluid, which has a relatively low impedance. In such instances, the number of electrical contacts applying the therapy may be decreased. In any of the foregoing embodiments once the responsive change has been made, the process can continue with process portion 251, which includes determining whether the new circuit produces a target impedance value. If so, then in process portion 238, the system delivers additional therapy. In addition, the system can notify the patient and/or practitioner of the update. If the change has not produced a target impedance value, the process returns to process portion 241. At that point, process portion 242 can be re-executed using a different combination of electrodes, or any of process portions 243-245 can be executed.

Process portion 243 includes changing the contacts that are active, for example, without increasing or decreasing the number of active contacts. In a particular example, process portion 243 can include substituting one contact for another. The substituted contact can be an anodic contact or a cathodic contact, and in some embodiments, both anodic and cathodic contacts can be changed. Once the contacts have been changed, the impedance is checked (process portion 251) and the process continues in a manner generally similar to that discussed above.

Process portion 244 includes adjusting the signal strength (increasing or decreasing the strength) in response to an indication that an impedance has changed. The signal strength can correspond to a voltage level, a current level, and/or a power level. Process portion 244 can in turn include selecting an updated strength value (e.g., an updated voltage value or current value) as shown in process portion 252, and then determining whether the updated strength value exceeds a predetermined compliance value (process portion 246). For example, a typical constant current source provides signals at a constant current by modulating the applied voltage, but keeping the applied voltage below a predetermined compliance voltage value, e.g., a programmed compliance voltage. If the selected updated strength value does not result in the compliance value being exceeded, then the impedance can optionally be rechecked in process portion 251 and the system can then deliver additional therapy (process portion 238). The impedance check at process portion 251 may be optional in this case because changing the signal strength may not change impedance.

If, in process portion 246 it is determined that the compliance value is exceeded by the selected updated strength value, then in process portion 247, the compliance value is adjusted. As discussed above, a constant current source automatically adjusts the applied voltage to account for at least some changes in the circuit impedance, so as to effectively produce a constant current. If the circuit impedance increases beyond a level that can be accommodated by a voltage change that remains within the maximum compliance voltage value, the compliance voltage can be adjusted, within preset limits that are established to provide for patient safety and comfort. Accordingly, in process portion 248, the system determines whether such a preset limit on the degree to which the compliance voltage can be adjusted has been exceeded. If it has not, then the impedance can optionally be checked (process portion 251) and the therapy delivered to the patient (process portion 238). If the necessary compliance value exceeds the preset limit, then in process portion 249, the user and/or the

practitioner can be notified that the recommended signal strength is not available without exceeding preset limits on the amount by which the compliance value can be changed. In addition to or in lieu of providing such notification, the process can automatically revert to one of the other available methods for adjusting the signal delivery parameters, including process portion 242 (changing the number of active contacts), process portion 243 (changing which contacts are active), and/or process portion 245 (changing other parameters). The other parameters that may be changed can include, but are not limited to, frequency, pulse width, and/or duty cycle.

In some embodiments, the compliance voltage value is increased, e.g., to account for an increased circuit impedance. In other embodiments, the compliance voltage value is decreased, e.g., in response to an impedance reduction. In any of the foregoing embodiments, it can be advantageous to keep the compliance value as low as possible, while still providing signals at an effective signal strength, so as to reduce the power consumed by the system. Accordingly, the system can automatically adjust the compliance margin (e.g., the difference between the compliance voltage and actual delivered voltage). For example, the system can automatically set the compliance margin to be a fixed level (in volts or millivolts) above the actual delivered voltage (e.g., the updated strength value). In other embodiments, the compliance margin can be a fixed percentage of the updated strength value. In still further embodiments, the compliance margin can vary, and can be automatically adjusted based on the range of requested strength perturbations, e.g., the degree to which the updated strength values deviate from the strength value being applied at that time. If the range is wide, the compliance margin can be correspondingly wide to avoid having to repeatedly adjust the compliance value. If the range is narrow, the compliance margin can be correspondingly narrow to reduce power consumption. Accordingly, in particular embodiments, the system can automatically track the foregoing perturbations and automatically adjust the compliance margin.

In particular instances, the foregoing arrangement can track the gradual reduction in the range of impedance perturbations that result when a newly implanted lead becomes "scarred in." The system can also track increases in the range of impedance perturbations if the scar tissue continues to build up in a manner that requires frequent upward adjustments in signal strength, and/or if the lead and/or patient undergo other changes that affect circuit impedance.

The systems and methods described above can operate in accordance with a variety of different modes. For example, during a first mode of operation, the system can check the impedance of one or more circuits that include only active therapy contacts. If, during the first mode of operation, the system identifies an impedance change in association with the active contact(s), it can then check the impedance of inactive contacts during a second mode of operation. Based on the impedance measurements obtained during the second mode, the system can automatically change which contacts are active and which are inactive. This arrangement can reduce the time and power required to perform an impedance check because inactive contacts are checked only when an impedance change is identified in association with one or more active contacts.

One feature of several embodiments described herein is that the system 100 can automatically identify changes in impedance via an implanted portion of the system, and automatically take appropriate action without patient or practitioner intervention. An advantage of this feature is that the

system need not rely on external analysis and/or diagnostics, and accordingly can implement the action more quickly and/or more conveniently.

Another feature of several of the embodiments described herein is that the system 100 can automatically identify an open circuit (e.g., a disconnected lead) and then gradually increase the strength of the applied therapy signal once the open circuit has been closed. An advantage of this feature is that it can reduce or eliminate the likelihood for the patient to feel a sudden shock or discomfort, which may otherwise result when the therapy signal is suddenly re-applied at the target strength value.

Still another feature of several of the embodiments described herein is that the system 100 can automatically adjust a preset compliance level (e.g., a voltage or current) to account for impedance changes. While increasing the compliance level may reduce overall system efficiency (e.g., may result in an increased power consumption), the patient can receive dynamically updated and effective therapy in a short period of time. This arrangement can allow the patient to continue receiving effective therapy until the power source is recharged or replaced, as opposed to potentially requiring that the patient undergo an in-office procedure to address the source of the impedance change (e.g., lead movement or scar tissue).

Yet another feature of several of the disclosed embodiments is that the system can detect impedance changes while the patient is receiving therapy. Accordingly, the patient's therapy need not be interrupted to provide this function. In addition, the system can not only check the impedance of the lead contacts applying therapy at a given time, but also other contacts. Accordingly, the system can readily identify alternate contacts that may be substituted for or provided in addition to the currently active contacts, to address changes in impedance. In addition, this arrangement allows the system to rapidly identify conditions that may affect contacts other than just the currently active contacts. Such conditions include a disconnected lead.

FIG. 4A is a schematic illustration of portions of the system 100 used for impedance detection in accordance with an embodiment of the disclosure. The system 100 can include an impedance detector 119 that in turn includes a microcontroller or microprocessor 107 that is coupled to an analog-to-digital (A/D) converter 112. The A/D converter 112 is coupled to a stimulation circuit 113 that includes one or more electrical contacts, and is implanted in the patient 190. Accordingly, the A/D converter 112 converts analog signals (e.g., voltage and/or current levels) to digital values, which are analyzed by the microprocessor 107 to identify impedance changes.

FIG. 4B is a representative circuit diagram of an embodiment of the system 100 described above with reference to FIGS. 1 and 4A. In this particular embodiment, the A/D converter 112 is connected to a voltage divider 114, which is in turn selectively couplable to the stimulation circuit 113 via an enable measurement switch 115. In other embodiments, the voltage divider 114 can be replaced with other suitable elements, for example, an amplifier. In any of these embodiments, the stimulation circuit 113 can include a constant current source 116 that receives a compliance voltage input 117, which can in turn be initially preset and then optionally adjusted within further preset limits, as discussed above. The constant current source 116 can be coupled to a contact selector 118, which is in turn connected to the contacts C1, C2 . . . C11 positioned at the patient 190. The contact selector 118 can include any of a wide variety of suitable switching devices used to select one or more of the contacts C1-C11 for

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applying therapy to the patient, and/or for impedance detection. The circuit can include an H-bridge or other suitable element to selectively reverse the current direction for one or more combinations of contacts C. In other embodiments, the system **100** can include other suitable arrangements, for example, a constant voltage source rather than a constant current source, a current sink in addition to the constant current source, and/or other suitable arrangements known to those of ordinary skill in the relevant art.

In any of the foregoing embodiments, the detector **119** will typically detect the impedance of a circuit that includes at least two contact, e.g., C1 and C2. If the circuit impedance increases beyond a preset threshold, the system can automatically step through the remaining contacts, e.g., C1 in combination with C3, C1 in combination with C4, and so on. This sequential process can be completed for any combination of contacts that may be suitable for continuing the patient therapy. In any of these cases, however, the impedance of the tested circuit will include the impedances of all the contacts in the circuit. Accordingly, the microprocessor **107** can include one or more of a variety of provisions for isolating impedance changes to a particular contact or contacts. For example, in one case, a nominal impedance can be assigned to other contacts included in the circuit (e.g., if multiple contacts are coupled in parallel in the circuit), and then subtracted from a total impedance to obtain the impedance for a given contact. In another embodiment, a series of multivariable equations can be used to solve for the impedance of each individual contact. Such an implementation is expected to consume more power than others, and accordingly, may in at least some embodiments be selected only when suitable power is available. In another approach, the microprocessor **107** can employ a successive approximation technique by using an initially measured value for one contact to estimate values for other contacts, and then repeating the process as the impedances of circuits with other contacts are identified. In any of the foregoing embodiments, the detector **119** obtains impedance values and/or changes in impedance values which are provided as inputs to other functional elements of the microprocessor **107** that automatically implement the changes described above with reference to FIGS. 2 and 3.

FIG. 5A illustrates a representative waveform **570a** having multiple pulses **571**, each with a cathodic phase **572** and an anodic phase **573** for delivering therapy to the patient. In a particular aspect of this embodiment, the waveform **570a** can be sampled directly (e.g., at the cathodic phase **572**) via the circuit described above with reference to FIG. 4B, to identify circuit impedance. For example, arrow S identifies a suitable sampling point. In particular embodiments, the waveform **570a** can be sampled at multiple points, and the results analyzed to provide a complex impedance value.

FIG. 5B illustrates another waveform **570b** having multiple bursts of pulses **571** separated by a quiescent period. In this embodiment, a separate detection pulse **574** can be superimposed on the waveform **570b** at the quiescent period. The impedance characteristics of the circuit are accordingly determined by analyzing the impedance associated with the detection pulse **574**. In still further embodiments, the detection pulse **574** can be applied to a circuit that is not applying therapy at that time, in which case the waveform **570b** is entirely quiescent except for the presence of the detection pulse **574**. In any of these embodiments, the detection pulse **574** is typically provided at subthreshold leads to avoid triggering a motor and/or sensory response in the patient.

In any of the foregoing embodiments, the therapy signal can be applied at frequencies ranging from about 1.5 kHz to about 100 kHz, duty cycles of from about 50% to about 100%,

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e.g., with the stimulation signal on for a period of about 10 milliseconds to about 2 milliseconds, and off for a period of about 1 millisecond to about 1.5 milliseconds. The applied pulses can have a width of from about 30 to 35 microseconds and an amplitude in the range of about 1 mA to about 4 mA. Other representative parameters are included in co-pending U.S. Provisional Application No. 61/176,868, incorporated herein by reference. In other embodiments, these parameters can have different values suitable for providing patient therapy to any of a variety of neural populations to address any of a variety of patient conditions.

FIG. 6 is a flow diagram illustrating a process **620** in accordance with another embodiment of the disclosure. Process **620** can include applying electrical therapy to the patient (process portion **625**), and automatically identifying changes in the impedance of an electrical circuit via which the therapy is applied, as a function of time (process portion **626**). Based on the information obtained in process portion **626**, process portion **627** can include predicting a future value of the impedance. For example, the future value can be predicted by a suitable extrapolation technique, including a linear or higher order function, a least-squares curve fit, or other technique. Based on the predicted future value of the impedance, process portion **628** can include automatically performing a task, e.g., without human intervention. Representative tasks can include predicting a lead failure, e.g., if the lead impedance intermittently becomes excessive. In other embodiments, process portion **628** can include predicting excessive impedance such as may result from the formation of scar tissue around a lead, for example, if the impedance exhibits a steady growth. Still another function that may be performed via process portion **628** includes confirming that the impedance trend identified in process portion **626** conforms with an expected trend, for example, an expected trend or schedule resulting from an expected amount of scar tissue growth. In still another embodiment, the task can include updating any of the signal delivery parameters described above, and/or adjusting the compliance values and/or compliance margins, as discussed above. In any of these embodiments, process portion **628** can include notifying the patient and/or practitioner, alone or in combination with any of the foregoing activities.

From the foregoing, it will be appreciated that specific embodiments of the disclosure have been described herein for purposes of illustration, but that various modifications may be made without deviating from the disclosure. For example, while certain aspects of the disclosure were described above in the context of spinal cord stimulation to treat chronic pain, similar techniques may be used in other embodiments to identify impedance changes and/or trends for therapy applied to other neural populations and/or for other patient conditions. The signal delivery parameters described above may have other values in other embodiments, for example, lower frequencies than the 1.5 kHz-100 kHz range described above. The detection circuits can have arrangements other than those specifically disclosed herein. The microprocessor can implement responses to the detected impedance changes using any of a variety of suitable programming languages and techniques.

Certain aspects of the foregoing disclosure described in the context of particular embodiments may be combined or eliminated in other embodiments. For example, the process of predicting impedance trends discussed above with reference to FIG. 6 may be combined with the process for adjusting impedance values described above with reference to FIGS. 2 and 3. The impedance values may be tracked in a manner that is coordinated with patient position or activity, as is disclosed

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in co-pending U.S. Provisional Application No. 61/151,464, incorporated herein by reference. The method of tracking impedance changes as a function of time and predicting future impedance values need not be performed by an implanted portion of the system in some embodiments, and can instead be performed outside the patient. Further, while advantages associated with certain embodiments have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the present disclosure.

We claim:

1. A patient therapy system, comprising:

an implantable pulse generator having a computer-readable medium, wherein the pulse generator is electrically coupleable to a signal delivery device to form an electrical circuit that includes an electrical contact carried by the signal delivery device, and wherein the computer-readable medium contains instructions that, when executed,

- (a) determine an impedance of the electrical circuit, and
- (b) in response to a decrease in the impedance, automatically adjust a therapy signal parameter in accordance with which an electrical signal is delivered via the electrical contact.

2. The patient therapy system of claim 1 wherein the computer-readable medium further contains instructions that, when executed, automatically decrease a strength of the electrical signal in response to the decrease in impedance.

3. The patient therapy system of claim 2 wherein the electrical contact is a first electrical contact, the signal delivery device further having a second electrical contact, and wherein the instructions, when executed, and in response to the decrease in the impedance, initiate delivery of a second electrical signal via the second electrical contact.

4. The patient therapy system of claim 1 wherein the computer-readable medium further contains instructions that, when executed, automatically decrease a voltage of the electrical signal in response to the decrease in impedance.

5. The patient therapy system of claim 1 wherein the computer-readable medium further contains instructions that, when executed, automatically decrease a current of the electrical signal in response to the decrease in impedance.

6. The patient therapy system of claim 1 wherein the computer-readable medium further contains instructions that, when executed, automatically stop delivery of the electrical signal via the electrical contact in response to the decrease in impedance.

7. The patient therapy system of claim 1 wherein the computer-readable medium further contains instructions that, when executed, determine an impedance trend based on identified changes in the impedance.

8. A patient therapy system, comprising:

an implantable pulse generator having a computer-readable medium, wherein the pulse generator is electrically coupleable to a signal delivery device to form an electrical circuit that includes an electrical contact carried by the signal delivery device, and wherein the computer-readable medium contains instructions that, when executed,

- (a) determine an impedance of the electrical circuit, and
- (b) in response to a decrease in the impedance, automatically adjust a therapy signal parameter in accordance with which a first electrical signal is delivered via the electrical contact, wherein determining the impedance of the electrical circuit includes determining the impedance via a second electrical signal, wherein the

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first electrical signal is a therapeutic electrical signal, and wherein the second electrical signal is a non-therapeutic electrical signal.

9. A patient therapy system, comprising:

an implantable pulse generator having a computer-readable medium, wherein the pulse generator is electrically coupleable to a signal delivery device to form a first electrical circuit that includes a first electrical contact carried by the signal delivery device and a second electrical circuit that includes a second electrical contact carried by the signal delivery device, and wherein the computer-readable medium contains instructions that, when executed,

- (a) determine an impedance of the first electrical circuit,
- (b) in response to a first increase in the impedance to a value less than a threshold value of impedance, automatically adjust a compliance value in accordance with which a first electrical signal is delivered via the first contact, wherein the threshold value of impedance is indicative of an open circuit, and wherein the compliance value corresponds to a value of impedance that is less than the threshold value of impedance, and
- (c) in response to a second increase in the impedance to a value greater than the threshold value of impedance, initiate delivery of a second electrical signal via the second contact.

10. The patient therapy system of claim 9 wherein the computer-readable medium further contains instructions that, when executed, measure the impedance of the first electrical circuit via a third electrical signal, wherein the first and second electrical signals are therapeutic, and wherein the third electrical signal is non-therapeutic.

11. The patient therapy system of claim 10 wherein the computer-readable medium further contains instructions that, when executed, and in response to the second increase in impedance, monitor the first electrical circuit for a decrease in impedance.

12. The patient therapy system of claim 11 wherein the computer-readable medium further contains instructions that, when executed, and in response to a decrease in the impedance below the threshold value, initiate delivery of the first electrical signal via the first electrical circuit.

13. The patient therapy system of claim 9 wherein the implantable pulse generator further includes a constant current source, and wherein the constant current source adjusts a voltage of the first electrical signal to maintain a current of the first electrical signal.

14. The patient therapy system of claim 9 wherein the computer-readable medium further contains instructions that, when executed, and in response to the second increase in impedance, provide a notification of an open circuit.

15. A patient therapy system, comprising:

an implantable pulse generator electrically coupleable to a signal delivery device having an electrical contact positionable to be in electrical communication with a target neural population of a patient when implanted;

an impedance detector disposed within the implantable pulse generator, the impedance detector operatively coupleable to an electrical circuit that includes the electrical contact to detect an impedance of the electrical circuit; and

a processor disposed within the implantable pulse generator, the processor having a computer-readable medium programmed with instructions that, when executed,

- (a) receive an indication of an impedance change from the impedance detector, and

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(b) based at least in part on the detected impedance change and without human intervention, automatically adjust a value of a signal delivery parameter in accordance with which the implantable pulse generator delivers an electrical signal to the electrical contact, wherein automatically adjusting a value of a signal delivery parameter includes automatically adjusting a compliance value in accordance with which the electrical signal is delivered, and wherein the compliance value corresponds to a value of impedance that is less than a threshold value of impedance.

16. The patient therapy system of claim **15** wherein the processor is programmed with instructions that, when executed, provide a notification that the value of the signal delivery parameter has been adjusted.

17. The patient therapy system of claim **15** wherein the implantable pulse generator includes a constant current source having a compliance voltage level with a first value, and wherein the processor further includes computer-readable instructions that, when executed,

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automatically increase the compliance voltage level from the first value to a second value higher than the first value, and

automatically increase a strength of the signal beyond a strength available with the first value.

18. The patient therapy system of claim **15** wherein the processor is programmed with instructions that, when executed, identify changes in impedance as a function of time.

19. The patient therapy system of claim **18** wherein the processor is programmed with instructions that, when executed, predict a future value of the impedance.

20. The patient therapy system of claim **15** wherein the signal delivery device includes a plurality of additional electrical contacts, and wherein the processor is programmed with instructions that, when executed, automatically changes the electrical contacts to which the electrical signal is applied, in response to the indication of an impedance change.

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